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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,796	06/27/2003	Charles J. Doillon	14363	5886

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EXAMINER	
BLANCO, JAVIER G	

ART UNIT	PAPER NUMBER
3738	

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09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,796	DOILLON ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 25-35* is/are pending in the application.

4a) Of the above claim(s) *6,7,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-15, 25, 26, and 29-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 29, 2007 has been entered.

Response to Amendment

2. Applicants' amendment of claims 1, 11, 29, and 31-33 in the reply filed on June 29, 2007 is acknowledged.

3. Applicants' addition of claims 34 and 35 in the reply filed on June 29, 2007 is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 8-10, and 29-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Takezawa et al. (EP 0 387 975; previously cited by the Examiner in PTO-892).

Takezawa et al. disclose a hydrated (throughout the mixture of chemical compounds, there is at least one step of hydration; in addition, see page 11, lines 15-20) membrane/substrate (see page 6, lines 48-50) applicable for prostheses/implants (see page 2, lines 15-19), wherein said hydrated membrane comprises a mixture of a biological polymer (e.g., collagen) and a polyacrylamide (e.g., PNIPAAm). See page 5, lines 21-60; page 10, line 50 to page 12, line 2 (including TABLE VI). The membrane/substrate further comprises a chemical crosslink (see page 7, lines-5-11). The claimed biological polymer:polyacrylamide ratio is shown in page 12, lines 1-2 (including TABLE VI). The membrane/substrate may comprise a bioactive compound. With regards to claim 29, since Takezawa et al. disclose a membrane/substrate comprising the same mixture as Applicants' AND having the same biological polymer:polyacrylamide ratio, it is inherent it will have similar values for the claimed physical properties (i.e., elastic modulus of less than 10 MPA, etc.).

NOTE: The recitation "corneal implant" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robei*, 88 USPQ 478 (CCPA 1951).

NOTE: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v.*

Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

6. With regards to the 102(b) rejection based on Takezawa et al. (EP 0 387 975; previously cited by the Examiner in PTO-892), Applicant's arguments filed June 29, 2007 have been fully considered but they are not persuasive.

a. The membrane/substrate of Takezawa et al. is applicable for prostheses/implants (see page 2, lines 15-19). The membrane/substrate is capable of been used for placement on/in the cornea.

b. The recitation "corneal implant" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robei*, 88 USPQ 478 (CCPA 1951).

c. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no

significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

d. Claim 1, as newly amended, is a product-by-process claim. [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See **M.P.E.P. 2113**. The end product/result (i.e., membrane/substrate) of Takezawa et al. is as claimed in claims 1-4, 8-10, and 29-33.

7. Claims 1, 4, 10, 15, 25, 26, 30-33 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chudzik et al. (US 6,410,044 B1).

Chudzik et al. disclose a corneal implant (see column 5, lines 15-27) comprising a hydrated (throughout the mixture of chemical compounds, there is at least one step of hydration; in addition, see column 7, lines 46-49) membrane, said hydrated membrane comprising a mixture of a biological polymer (e.g., gelatin, collagen, fibronectin, laminin, elastin, etc.; see column 7, lines 55-63) and a polymer of an acrylamide (e.g., polyacrylamide; see entire document). The matrix/membrane is disclosed as further comprising a chemical crosslink. Since the matrix/membrane is added to a prosthesis (e.g., corneal implant), the entire article/device comprises at least two layers (i.e., matrix/membrane + corneal implant; together forming a

corneal implant). The corneal implant is intended to be applied to a human being. The membrane may comprise a bioactive compound.

Response to Arguments

8. With regards to the 102(e) rejection based on Chudzik et al. (US 6,410,044 B1), Applicant's arguments filed June 29, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue: "the corneal implant of the instant invention comprises a membrane produced only by mixing a biological polymer, such as collagen, with polyacrylamide" (emphasis added). However, it is noted the independent claim 1 recite "comprising", which is an open ended transitional phrase. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369,

1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004). "Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.; *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986).

b. The corneal implant disclosed by Chudzik et al. comprises a membrane/substrate that comprises (as indicated in the 102 rejection above) a mixture of a biological polymer and a polyacrylamide. The components of said membrane/substrate are described together as a polymerization mixture.

c. Claim 1, as newly amended, is a product-by-process claim. [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See **M.P.E.P. 2113**. The end product/result (i.e., membrane/substrate) of Chudzik et al. is as claimed in claims 1, 4, 10, 15, 25, 26, 30-33.

9. Claims 1, 2, 4, 8, 10, 25, 26, and 30-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Manesis (US 5,401,508 A).

Manesis discloses a corneal implant (see Abstract; column 5, lines 5-25) comprising a hydrated (throughout the mixture of chemical compounds there is at least one step of hydration) membrane/substrate, said membrane comprising a mixture (see column 47-63) of a biological polymer (e.g., cytophilic components such as collagen, fibronectin, laminin, proteins, growth factors, etc.; see column 6, lines 1-14) and a polymer of an acrylamide (e.g., at least one member selected from N, N-dimethylacrylamide, N, N-diethylacrylamide, N-methyl, N-ethylacrylamide; see column 2, lines 25-43; column 3, lines 15-22). The matrix/membrane is disclosed as further comprising a chemical crosslink (see column 4, lines 18-29). The corneal implant is intended to be applied to a human being. The membrane may comprise a bioactive compound (e.g., drug; see column 5, lines 18-25).

Claim 1, as newly amended, is a product-by-process claim. [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See **M.P.E.P. 2113.**

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 5, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. (US 6,410,044 B1) in view of Perez et al. (WO 94/17851 A1; previously cited by the Examiner in PTO-892).

Chudzik et al. disclose the invention as claimed except for particularly disclosing the use of telocollagen or atelocollagen, and the claimed membrane thickness. However, this is already known in the art. For example, Perez et al. disclose a corneal implant comprising a membrane (i.e., film or layer: see Abstract; see page 8, lines 16-18; page 12, lines 34-37), said membrane comprising a biological polymer (e.g. collagen type I, modified forms of collagen,

glycosaminoglycans: see Abstract; page 13, lines 18-36; claims 1-5) and a hydrogel (e.g., polyacrylamide: see Abstract; page 11, lines 8-12; claims 1-5) having a biological polymer to polyacrylamide ratio as disclosed at page 11, lines 31-32 and having a membrane thickness as disclosed at page 11, lines 32-34, and page 12, lines 34-37 in order to provide "a suitable substrate for corneal epithelial cell growth while maintaining the desirable characteristics of hydrogels, i.e., clarity, flexibility, and ability to allow diffusive flow of materials" (see Abstract; page 7, lines 26-37; page 8, lines 20-24). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a corneal prosthesis comprising collagen type I or modified forms of collagen, and a membrane thickness of about 50 microns to about 100 microns, as taught by Perez et al., with the corneal implant of Chudzik et al., in order to provide a suitable substrate for corneal epithelial cell growth while maintaining the desirable characteristics of hydrogels, i.e., clarity, flexibility, and ability to allow diffusive flow of materials.

12. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. (US 6,410,044 B1) in view of Graham et al. (US 5,433,745; cited in Applicants' IDS).

Chudzik et al. disclose the invention as claimed except for particularly disclosing the particular cross-linking agents disclosed in claims 11 and 12. However, this is already known in the art. For example, Graham et al. disclose a corneal implant comprising a membrane (i.e., film, coat, or layer), wherein said membrane comprising a biological polymer (e.g. coating of a cytophilic component such as collagen, fibronectin, etc: see column 5, lines 11-35; column 10,

lines 39-43) and a hydrogel (e.g., polyacrylamide: see column 3, lines 34-59), and wherein said membrane further comprises a chemical crosslink (e.g., 1-(3-dimethylaminopropyl)-3-ethyl carboddimide or EDC: see column 6, lines 46-67; TABLE 3) in order to provide a suitable substrate for corneal epithelial cell growth (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a corneal prosthesis comprising 1-(3-dimethylaminopropyl)-3-ethyl carboddimide or EDC, as taught by Graham et al., with the corneal implant of Chudzik et al., in order to provide a suitable substrate for corneal epithelial cell growth.

13. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. (US 6,410,044 B1) in view of Takezawa et al. (EP 0 387 975 A1; previously cited by the Examiner in PTO-892)).

Chudzik et al. disclose the invention as claimed, including the use of polyacrylamides, except for particularly disclosing using poly(N-isopropylacrylamide) [i.e., PNIPAAM] as the polyacrylamide. However, this is already known in the art. For example, Takezawa et al. disclose a prosthesis (see page 2, lines 17-18) comprising a membrane/film (see page 6, lines 48-49; see claim 9) comprising a collagen-PNIPAAM conjugate (see page 5, page 11, and page 12) in order to provide a cell growth subs.trate having high cell density and cellular function, and having excellent self-supporting abilities (see Abstract; see page 2, lines 3-11; see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a prosthesis comprising a membrane/film comprising a collagen-PNIPAAM conjugate, as taught by Takezawa et al., with the corneal

implant of Chudzik et al., in order to provide a cell growth substrate having high cell density and cellular function, and having excellent self-supporting abilities.

14. Claims 15, 29, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik et al. (US 6,410,044 B1).

Chudzik et al. disclose the invention as claimed. Chudzik et al. did not particularly disclose the claimed values of the physical properties claimed in claim 29. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the corneal implant of Chudzik et al. with a particular/specific values of physical properties since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 15, intraocular and/or corneal implants comprising a plurality of membranes (i.e., layers, films, laminates, etc.) are well known in the art and would have been obvious in view of a patient's condition/disease, with the ordinary practitioner having been left to select a particular number of membranes based on the intended purpose (e.g., different layers may provide (i) different refractive properties; (ii) site for epithelial cell adhesion/attachment; (iii) modifying the curvature of the cornea; etc.).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Javier G. Blanco

September 11, 2007

David H. Willse
Primary Examiner